UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,330	11/22/1999	STEPHEN A. JOHNSTON	UTSD:681	4922

7590 07/29/2003

STEVEN L. HIGHLANDER
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVENUE
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/448,330	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34, 36, 37, 41- 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34, 36, 37, 41- 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This office action is in response to Amendment C, paper #13, filed February 11, 2003. The following claims are pending: 34, 36, 37, and 41- 65.

Declaration

The declaration of Dr. Stephen Johnson has been fully considered and not found persuasive.

The declaration has been submitted to overcome rejections based on the prior art that the invention was anticipated. The declaration presents arguments that:

- ELI induces a diverse immune response, this technique was not known in those of skill in the art,
- a unique antibody composition is produced based on antigens from known and unknown sources, and
- there was doubt the method was feasible for the following reasons 1) bacterial genes do not sufficiently express in mammalian cells, 2) any expression would be too low to elicit an immune response, 3) ELI would only work in a natural host/pathogen system, 4) indifference or dominance would prevent the expression of valuable antigens in mixtures, 5) induction of immunity would block protection, and 6) tolerance would be produced by low level expression of pathogen genes.

It appears that the declaration was submitted in response to rejections over the prior art that the invention was anticipated or in the alternative that the invention was obvious. While not explicitly referring to the declaration, Applicant's argument regarding of "unique antibody composition" appears to derive support from the declaration. The Declaration was submitted in a parent of the parent of the instant application (related as a divisional), that issued as US 5,703,057 claiming a method of making a sib library.

The claims are drawn to antibodies. The broadest claim (claim 34) is drawn to "antibodies *obtained by administering to an animal clones from a sib library of an expression library prepared from DNA of a selected cell or synthetic DNA and collecting antibodies generated in response to an antigen or antigens expressed from said DNA*." (Italics added)

It is noted that the portion of claim 34 shown in italics define the claimed product as a product by process."

The declaration fails to persuade. It is not commensurate in scope with the pending claims. The claims are not drawn to methods, *per se*, nor were they rejected on enablement issues of bacterial genes not expressing in cells, levels of immune responses, ELI would work only in a natural pathogen/host system, interference and/or dominance would prevent expression of valuable antigens or tolerance is/would be produced by low level expression of pathogen genes.

The pages headed "BACTERIAL GENES WOULD NOT SUFFICIENTLY EXPRESS IN MAMMALIAN CELLS." and "THE LEVEL OF EXPRESSION WOULD BE TOO LOW TO ELICIT AN IMMUNE RESPONSE" appear to be directed against a

rejection based on enablement, but no such rejection was made. Furthermore, there are no limitations in the claims directed to the number of genes that can be screened, the level of sensitivity to produce a response, or that ELI is optimized for bacterial genes. There is nothing in the claims about bacterial open reading frames, or divergent bacterial codon usage.

The pages headed "ELI WOULD ONLY WORK IN NATRURAL....", "INTERFERECE AND/OR DOMINANCE WOULD PREVENT EXPRESSION", and "TOLERANCE WOULD BE PRODUCED..." also appear to be directed against a rejection based on enablement, but no such rejection was made. There is also nothing in the claims that the antibodies are required to induce protection. There is also nothing in the claims or in the specification (page 5, lines 20- 27) that require more than one gene to be used as an immunogen.

With regard to the point that the product made by the method produces a "unique composition of antibodies", there is nothing in the claims that requires a "unique composition" that limit the meaning of the claims to those characteristics (page 5, lines 20- 27). Furthermore, there is no specific evidence in the declaration that antibodies made by the disclosed method can be differentiated from the antibodies of the prior art.

Finally, declarant indicates what others thought. The inventor may provide expert testimony to what he or she thinks but not on what others think.

Rejections Withdrawn

The rejections of claims 34, 36, 37, and 41- 65 under 35 U.S.C. 112, second paragraph.

The rejections of claims 34, 36, 41- 65 under 35 U.S.C. 112, first paragraph.

Rejection Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34, and 57- 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Pietromonaco (PNAS 1990, Vol 8, pages 1811- 1815).

Applicant argues that the claim is directed to "Antibodies obtained by administering to an animal clones from a sib library of an expression library prepared from DNA of a selected cell or synthetic DNA and collecting antibodies generated in response to an antigen or antigens expressed from said DNA." That Pietromonaco does not teach "pathogen" in the way that it is used in the claims, that Pietromonaco is an indirect *in vitro* screen and not useful *in vivo*, the output of ELI is protection against infection, that ELI is useful in high throughput screening and that a unique collection of antibodies is obtained by ELI. Also the declaration was cited to support additional arguments. The declaration is summarized above.

Applicant's arguments have been fully considered and not found persuasive.

There is no limitation in the claim or in the definition of sib library (page 5, lines 20- 27) that require more than one gene and "clones" is more than one unit of DNA but it can be multiple copies of the same DNA. There is nothing in the claims about protection from infection, that the antibody must be useful in vivo, or that the process must be high throughput. There is no argument that the unique properties of the antibodies that are differentiable from the prior art antibodies. The declaration as discussed above is not persuasive in that it does not differentiate the antibodies from prior art antibodies and that it is not commensurate in scope with the invention as now claimed.

The rejection of record is maintained.

Claim Rejections - 35 USC § 102/ 103

Claims 34, 41, 42, and 56- 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fynan (PNAS 1993, Vol 90, pages 11478- 11482).

Fynan teaches an antibody against influenza made by genetic immunization (abstract).

Applicant argues that the reference is drawn to "*an antibody*" and that "again as indicated above the method recited in claim 34 results in a unique antibody composition,

based on antigens from known and unknown sequences. The cited reference does not teach or suggest the composition or the method for creation thereof."

Applicant's arguments have been fully considered and not found persuasive.

The referenced antibody would be recognized by one of skill in the art to be more than one antibody and that not all the antibodies would be identical. The claims are in fact drawn to antibodies, a product, not to a method or a method for creation. For reasons discussed above and in the 102 rejection above, the antibodies meet the limitation of the claims. The rejection is maintained.

Claims 34, 43, and 56- 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conry (Cancer Research 1994 Vol. 54, pages 1164- 1168).

Conry teaches an antibody against a cancer antigen (abstract, Figure 1, and Table 4).

Claims 34, 43, and 56- 60 are are drawn to an antibody which is described by the process used to make it. However, the production process does not confer any distinguishing characteristics upon the resulting antibody. Therefore, any antibody directed against the same antigen reasonably appears to be the same or similar as the antibody made by Applicant's process.

Applicant argues that the reference does not teach the claimed antibodies and that "again as indicated above the method recited in claim 34 results in a unique antibody composition, based on antigens from known and unknown sequences. The

method by which the antibody composition is made was neither known or obvious to those of skill in the art at the time the invention was made.

Applicant's arguments have been fully considered and not found persuasive.

The claims are not drawn to an antibody compostion and the method by which the antibodies were made is not what is currently claimed. The claims are in fact drawn to antibodies, a product, not to a method. For reasons discussed above and in the 102 rejection above, the antibodies meet the limitation of the claims.

The rejection of record is maintained.

Claims 34,36, 37, 41, 44- 50, 52- 55, 56,and 61- 65 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Butman (US 4,950,589).

Applicant argues that the reference does not teach the claimed antibodies and that "again as indicated above the method recited in claim 34 results in a unique antibody composition, based on antigens from known and unknown sequences. The method by which the antibody composition is made was neither known or obvious to those of skill in the art at the time the invention was made.

Applicant's arguments have been fully considered and not found persuasive.

The claims are not drawn to an antibody composition and the method by which the antibodies were made is not what is currently claimed. The claims are in fact drawn to antibodies, a product, not to a method. For reasons discussed above and in the 102 rejection above, the antibodies meet the limitation of the claims.

The rejection of record is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
July 28, 2003

JAMES HOUSEL 7/28/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600